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10/050,188	01/14/2002	Tracy L. Ferea	07414.0055-00000	6282

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EXAMINER

CHAKRABARTI, ARUN K

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 12/15/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

100

Office Action Summary

Application No.
10/050,188

Applicant(s)
Ferea

Examiner
Arun Chakrabarti

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1634



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Nov 20, 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 and 26-32 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 and 26-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 1103 6) ☒ Other: Detailed Action

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DETAILED ACTION

Current Status of the Application

1. Applicant's amendment filed on November 20, 2003, has been entered. Claims 1, 10, and 26 have been amended. New claims 27-32 have been added.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1-9, and 26-29 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 1-9, and 26-29 are rejected over the recitation of the negative limitations "wherein at least one of the features does not comprise a control-specific probe" (See MPEP 2173.05 (I)) - "Any negative limitation or exclusionary proviso must have basis in the original disclosure. See *Ex parte Grasselli*, USPQ 393 (Bd. App. 1983), *aff'd mem.*, 738 F.2d 453 (Fed. Cir. 1984). The mere absence of a positive recitation is not basis for an exclusion. Any claim containing a negative limitation which does not have basis in the original disclosure should be rejected under 35 U.S.C.

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112, first paragraph as failing to comply with the written description requirement". In the instant application, negative limitations inserted in the amended claims do not have any expressed basis in the original specification (as described in page 5, paragraph 10; page 8, paragraph 27).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 1-10 and 26-32 are rejected under 35 U.S.C. 103(a) as being obvious over Brink et al. (U.S. Patent 5,563,034) (October 8, 1996) in view of McMillan (U.S. Patent 6,312,929 B1) (November 6, 2000).

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Brink et al teaches a method for detecting the presence or absence or amount of an experimental target-specific probe on a substrate (Abstract) comprising:

(a) exposing a substrate containing a first feature comprising an experimental target-specific probe and a control-specific probe to a labeled control target, such that the labeled control target binds specifically to control-specific probe bound to the substrate (Claim 1 and Column 9, lines 15-32), and

(b) measuring a signal from labeled control target bound to control-specific probe to determine the presence or absence or amount of experimental probe (Claim 1 and Column 9, lines 15-32). This rejection is based on the fact that labeled negative control nucleic acid probes of Brink et al can be considered broadly as control target or experimental target nucleic acids and vice versa in absence of a clear definition of a target and the probe either in the specification or in the claim of the instant application.

Brink et al teaches a method, wherein the experimental target-specific probe and a control-specific probes are polynucleotides (Abstract).

Brink et al teaches a method, wherein the control-specific probes that are polynucleotides contain synthetic non-Watson-Crick bases (Figure 4 and Column 6, lines 45-63).

Brink et al teaches a method, wherein the control-specific probes are attached or not attached to the experimental target-specific probe (Column 5, lines 28-35).

Brink et al teaches a method, wherein the labeled control target comprises a fluorophore (Column 9, lines 6-8).

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Brink et al teaches a method, wherein the substrate is exposed to a labeled experimental target molecule in a sample, such that labeled experimental target molecule is bound to experimental target-specific probe (Column 9, lines 15-32).

Brink et al teaches a method, wherein the signal from labeled control target bound to control-specific probe is used to quantitate the amount of labeled experimental target in a sample (Column 11, lines 22-26).

Brink et al teaches a method, wherein the substrate further contains a second feature comprising a second experimental target-specific probe and the control specific probe (Column 8, line 27 to Column 9, line 14).

Brink et al teaches a method for detecting the presence or absence or amount of an experimental target probe on a substrate (Claim 1 and Column 8, line 27 to Column 10, line 55) comprising:

(a) exposing a substrate containing a feature comprising an experimental target probe to a labeled control target, such that the labeled control target binds to experimental target probe bound to the substrate (Claim 1 and Column 9, lines 15-32), and

(b) measuring a signal from labeled control target bound to experimental target probe to determine the presence or absence or amount of experimental probe (Claim 1 and Column 9, lines 15-32).

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Brink et al teaches a method for determining the relative amount of two different experimental target nucleic acid sequences in a sample (Column 11, line 64 to Column 12, line 25), comprising:

providing a nucleic acid array, wherein the array comprises a first feature that comprises first experimental target-specific probes that are complementary to a first experimental target sequence and control-specific probes that do not hybridize to experimental target sequences, and a second feature that comprises second experimental target-specific probes that are complementary to a second experimental target sequence and control specific probes that do not hybridize to experimental target sequences (Column 11, lines 3-35);

contacting the array with:

(1) a sample that includes experimental target sequences that are labeled with a first label; and

(2) synthetic control target sequences that are labeled with a second label and that hybridize to the control-specific probes on each of the first and second features, but that do not hybridize with the experimental target-specific probes (Column 12, line 40 to Column 13, line 45);

determining the intensity of any signal from the first and second labels in the first and second features (Column 15, lines 28-45); and

determining the ratio of the intensity of the signal from the first label to the intensity of the signal from the second label for each of the first and second features; and

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comparing the ratios of the intensity of the signal for the first and second features to calculate the relative amount of the first and second experimental nucleic acid target sequences in the sample (Column 15, lines 28-45).

Brink et al does not teach a method, wherein the substrate contains two or more features and wherein at least one of the features does not comprise a control-specific probe.

McMillan teaches a method, wherein the substrate contains two or more features and wherein at least one of the features does not comprise a control-specific probe (Figure 1, Column 5, line 36 to Column 6, line 63 and Column 12, line 66 to Column 13, line 30 and claims 1-12).

Brink et al. does not teach a method, wherein there is a labeled experimental target and wherein the labeled control target competes with the labeled experimental target for binding to the experimental target probe.

McMillan teaches a method, wherein there is a labeled experimental target and wherein the labeled control target competes with the labeled experimental target for binding to the experimental target probe (Figure 1, Column 5, line 36 to Column 6, line 63 and Column 12, line 66 to Column 13, line 30 and Table 1 and Example).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to combine and substitute the method, wherein the substrate contains two or more features and wherein at least one of the features does not comprise a control-specific probe of McMillan into the method of Brink et al. , since McMillan states, “Thus, each amplification product provides a target for at least one corresponding probe that is useful for

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detecting and quantifying the amplification products (Column 6, lines 12-15).” An ordinary practitioner would have been motivated to combine and substitute the method, wherein the substrate contains two or more features and wherein at least one of the features does not comprise a control-specific probe of McMillan into the method of Brink et al., in order to achieve the express advantages noted by McMillan, of an invention which is useful for detecting and quantifying the amplification products.

Response to Amendment

6. In response to amendment, previous 102 (b) rejection has been withdrawn. However, a new 112(first paragraph) and 103(a) rejection have been included.

Response to Arguments

7. Applicant's arguments with respect to all pending claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Arun Chakrabarti, Ph.D. whose telephone number is (703) 306-5818. This phone number will be changed to (571) 272-0740 on and from January 14, 2004. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (703) 308-1119. Any inquiry of a general nature or relating to the status of this application should be directed to the Group LIE Chantae Dessau, whose telephone number is (703) 605-1237. Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission via the P.T.O. Fax Center located in Crystal Mall 1. The CM1 Fax Center numbers for Technology Center 1600 is (703) 872-9306. Please note that the faxing of such papers must conform with the Notice to Comply published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Arun Chakrabarti

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Arun K. Chakrabarti
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PATENT EXAMINER
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December 11, 2003

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